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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,389	07/18/2001	Hitoshi Endou	55562	8159

21874 7590 08/29/2005

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,389

Applicant(s)

ENDOU ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/5/04; 01/7/02; 3-3-61</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, claims 1-6, species SEQ ID NO:6 in the reply filed on March 2, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-6 pending. Claims 7-59 cancelled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

The claims are directed to an amino acid transporter. The specification as filed does not disclose or provide evidence that points to a property of the claimed transporter such that another non-asserted utility would be well established. The specification on page 4 disclose the asserted utility of using the claimed transporter because transporter is associated with disorders. However, there is no nexus between the transporter claimed and the treatment of the

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diseases because the disorders are associated with other transporters which have different function from the currently claimed transporter. Thus, the treatment of the disease lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Any utility of the antibody directed to the receptor protein or other specific asserted utility is directly dependent on the function of the receptor protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The method of using the orphan receptor polypeptide does not have well established utility because different receptors would have different functions and the skilled artisan would have to determine the function of the orphan receptor. The claimed polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the receptor protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the receptor protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The vectors, host cells, and the process of expressing the protein do not have utility because the nucleic acid without utility is needed to practice the inventions. . The specification as filed does not disclose or provide evidence that points to a property of the claimed protein such that another non-asserted utility would be well established.. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is

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required. Thus, the asserted utility lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search, but compensation for its successful conclusion."

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology

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Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaugitsch et al. (JBC, 1992 (AL)).

Gaugitsch et al. disclose a protein which has 100% amino acid sequence identity with the claimed SEQ ID NO:2. The protein inherently has the function of the the transporter and interaction with other proteins such as 4F2hc proteins.

5. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman (US 5,843,727).

Hillman et al. disclose a protein which is 100% amino acid identical to SEQ ID NO:2 and 4 from amino acid 272-512. The protein inherently has the function of the transporter and interaction with other proteins such as 4F2hc proteins.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through

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Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0507.

A handwritten signature in black ink, appearing to read "Michael D. Pak".

Michael Pak
Primary Patent Examiner
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9 June 2005